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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,514	04/30/2001	K. Roger Aoki	D2929CON	3428

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EXAMINER

FORD, VANESSA L.

ART UNIT PAPER NUMBER

1645

DATE MAILED: 01/13/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/845,514

Applicant(s)

AOKI ET AL.

Examiner

Vanessa L. Ford

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-9, 17-20 and 22-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-9, 17-20 and 22-28 is/are rejected.
- 7) ☒ Claim(s) 5, 21 and 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. Applicant's response, Exhibit A and B received September 24, 2002 are acknowledged. This Office Action is responsive to Applicant's response filed September 24, 2002. For purposes of clarification, this application was filed on April 30, 2001 and the post-AIPA version of 35 U.S.C. 102(e) applies to the instant application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

### ***Rejections Withdrawn***

3. In view of Applicant's amendment the rejection of claims 1-9 and 17-29 under 35 U.S.C. 102/103, pages 5-6, paragraph 7 of the previous Office action is withdrawn.

### **Rejections Maintained**

4. The rejection of claims 1-4 and 6-9 under 35 U.S.C. 102(e) is maintained for the reasons set forth on pages 3-4, paragraph 5 of the previous Office Action.

The rejection was on the grounds that Arnon teaches a method of providing toxin therapy to a human patient who has a neuromuscular disorder comprising administering a therapeutically effective amount of botulinum toxin (column 12, lines 4-7). Arnon teaches that various botulinum toxin combinations are used in the invention (column 14, lines 1-9). Characteristics such as duration of treatment for therapeutic activities would be inherent in the method of Arnon.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material

Art Unit: 1645

method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges "that U.S. Patent 5,562,907 was filed June 1994 as a continuation –in-part of U.S. application No. 08/962,110 (the '110 application) filed on May 14, 1993. As discussed herein, the disclosure in the '907 patent regarding combinations of botulinum toxins was new matter that was added to the '110 application via the continuation-in-part application, which is now the '907 patent. Accordingly, the disclosure regarding combinations of botulinum toxins in the '907 patent is **not** entitled to the May 14, 1993 priority date and thus, the disclosure of combination of botulinum toxins has an **effective filing date of June 6, 1994**. Because the instant application has an effective filing date of June 10, 1993, the instant application predates the disclosure of the combinations of botulinum toxins of the '907 patent. Accordingly, the **'907 patent is not prior art** with respect to the claimed invention".

Applicant's arguments filed September 24, 2002 have been fully considered but they are not persuasive. U.S. Patent 5,562,907 was filed June 6, 1994. However, it has an effective filing date of May 14, 1993. The Examiner disagrees with Applicant's assertion that U.S. Patent 5,562,907 is not prior art. Applicant is directed to page 19 of U.S. application no. 08/962,110 which teaches combinations of botulinum toxin. It is the position of the Examiner that U.S. Patent 5,562,907 is prior art. It should be remembered that the instant application has an effective filing date of June 10, 1993. Therefore, the prior art reference anticipates the claimed method.

Art Unit: 1645

5. The rejection of claims 17-20 and 22-28 under 35 U.S.C. 102(e) is maintained for the reasons set forth on pages 4-5, paragraph 6 of the previous Office Action.

The rejection was on the grounds that Arnon teaches that various botulinum toxin combinations are used in the invention which include botulinum types A, B, C, D, E, F and G (column 14, lines 1-9). Limitations such as "treatment for joint dislocations, relaxation for physical therapy, alleviation of muscle spasm, immobilization of a joint undergoing surgery, for prevention of muscle contractions prior to or after surgery, treating tendon and ligament repair, treatment of scoliosis and spasm of sphincter muscles" are being viewed as limitation of intended use.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges "that U.S. Patent 5,562,907 was filed June 1994 as a continuation –in-part of U.S. application No. 08/962,110 (the '110 application) filed on May 14, 1993. As discussed herein, the disclosure in the '907 patent regarding combinations of botulinum toxins was new matter that was added to the '110 application via the continuation-in-part application, which is now the '907 patent. Accordingly, the disclosure regarding combinations of botulinum toxins in the '907 patent is **not** entitled to the May 14, 1993 priority date and thus, the disclosure of combination of botulinum toxins has an **effective filing date of June 6, 1994**. Because the instant application has an effective filing date of June 10, 1993, the instant application predates the disclosure of the combinations of botulinum toxins of the '907 patent. Accordingly, the **'907 patent is not prior art** with respect to the claimed invention".

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Art Unit: 1645

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### **Status of Claims**

6. Claims 5, 21 and 29 appear to free of the prior art. Claims 5, 21, and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


Art Unit: 1645

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

  
Vanessa L. Ford  
Biotechnology Patent Examiner  
January 6, 2002

  
**LYNETTE R. F. SMITH**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**